IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	Case No. 1:14-cv-1748 MDL No. 2545 Hon. Matthew F. Kennelly
THIS DOCUMENT RELATES TO ALL CASES	

JOINT STATUS REPORT REGARDING CMO 87 TRIAL GROUP 1 CASES

The parties submit this joint status report pursuant to the Court's Minute Order (Document No. 2715), directing them to advise the Court if either side believes that any of the cases in Trial Group 1 is a case that: (a) involves prescription of AndroGel to a patient with a medical condition specifically listed in the label; and/or (b) is subject to a defense applicable to the particular Plaintiff, including but not limited to a statute of limitations or statute of repose.

PSC Position and Response on the CMO 87 Trial Group 1 Cases:

In response to the Court's two inquiries about whether each CMO 87 Trial Group 1 Plaintiff, "involves a prescription of AndroGel to a patient with a medical condition specifically listed in the label," (i.e., whether it was "off-label") and/or whether the case is subject to a defense, "including but not limited to a statute of limitations or statute of response," the PSC hereby responds as follows and also provides brief factual summaries surrounding each of the six (6) CMO 87 Trial Group 1 cases.

1. **Dominick Papandrea,** 14-cv-08948 – Plaintiff Pick

A. Case Overview

Dominick Papandrea was first prescribed AndroGel 1.62% on September 13, 2012 by his primary care physician after reporting he was "very fatigued." He was 62 years old at the time. A single blood test revealed that his testosterone level was 304. Mr. Papandrea was not diagnosed with hypogonadism. Mr. Papandrea filled his one and only prescription for AndroGel 1.62% on September 24, 2012 and began using it as instructed.

On November 16, 2012, while still taking AndroGel 1.62%, Mr. Papandrea presented to the hospital and reported chest tightness for a few days. He was diagnosed with and then treated for an acute anterior wall ST-elevation myocardial infarction secondary to 100% occlusion of the proximal left anterior descending artery. Mr. Papandrea stopped taking AndroGel after his heart attack. This is the only heart attack that he has experienced. He has since been diagnosed with multiple myeloma, which is currently in remission. Mr. Papandrea's prescriber testified that based on his knowledge and prescribing practices today, he likely would not have prescribed testosterone to Mr. Papandrea.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Mr. Papandrea lived in Brick, New Jersey, at all relevant times. He was prescribed and took AndroGel in New Jersey and he suffered his heart attack in New Jersey. Mr. Papandrea filed his complaint on November 7, 2014, less than two years after suffering his myocardial infarction and within New Jersey's two-year statute of limitations for personal injury actions. A few years later, Mr. Papandrea moved to Florida, where he now resides.

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Mr. Papandrea's AndroGel prescription was off-label as there is no evidence that he had either primary or secondary hypogonadism. Mr. Papandrea was prescribed AndroGel 1.62% based on (1) his report that he was "very fatigued" and (2) a single testosterone level reading of 304. He does not have congenital hypogonadism and has not otherwise been diagnosed with any condition that would cause him to have acquired hypogonadism.

2. Edwin Harris, 14-cv-0796 – Plaintiff Pick

A. Case Overview

In 2012, Colonel Edwin Clay Harris (U.S. Army, retired) saw multiple television advertisements for AndroGel, prompting him to ask his urologist, Dr. Allen Futral, to prescribe AndroGel. Dr. Futral prescribed AndroGel on August 14, 2012. He did not warn Col. Harris about the risk of stroke or heart attack based on the information available to him at the time. In contrast, today with the benefit of more recent disclosures like the mandated FDA label change, Dr. Futral testified that if he was prescribing AndroGel to Col. Harris, he would have, at minimum, warned about the risk of stroke – that is, if he would have prescribed it at all. If Dr.

Futral had warned Col. Harris, the Plaintiff testified that he would never have taken AndroGel. Further, there is not a single medical-test record showing that Col. Harris had low testosterone in 2012 before being prescribed AndroGel.

About 60 days after starting AndroGel, while on vacation with his wife and sister-in-law, Col. Harris suffered an ischemic stroke resulting in permanent physical damage to his brain. Col. Harris has suffered memory loss, trouble finding the right words, and other symptoms since his stroke. Although Col. Harris has a history of hypertension and hyperlipidemia, he has been on medications for years to control these conditions. He is described by his primary care physician as a compliant patient, who follows all directions, takes his medications, and seeks prompt medical advice when there is a concern. He did not suffer a stroke or other cardiovascular event before using AndroGel and has not suffered one since he ceased using it after his stroke.

Likely owed to the memory loss caused by his stroke, Col. Harris has no recollection of using AndroGel in 2004. According to medical records produced at his primary care physician's deposition, he was prescribed AndroGel for a few months and may have showed "minimal" benefits before use was discontinued. While his prescriber may have discussed the potential need to check hematocrit levels in 2004, he did not warn about the risk of stroke or cardiovascular event, although he does discuss such warnings with his patients today.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Col. Harris' case was filed on October 13, 2014 within the Georgia 2-year statute of limitations which was calculated from October 15, 2012, the date he first had symptoms of a stroke. (*See* O.C.G.A. § 9-3-33).

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Col. Harris's AndroGel prescription was off-label as there is no evidence that he had either primary or secondary hypogonadism. Moreover, as noted above, there is a lack of any test even showing that Col. Harris had low testosterone when he was prescribed AndroGel. Nor has Col. Harris been diagnosed with hypogonadism since he stopped using AndroGel.

3. Edward Natale, 16-cv-05706 – Plaintiff Pick

A. Case Summary

Mr. Natale is a veteran of the United States Air Force, who suffered a thrombotic ischemic stroke at age 68 as a result of using AndroGel 1.62% ("AndroGel"). He was first prescribed AndroGel at age 65 by Stephen Humbert, MD, on January 20, 2012 and used it until the time of his stroke in June 2014. On June 9, 2014, he was admitted to the hospital with complaints of left facial numbness, left leg numbness, and sensory deficits. He was diagnosed with and then treated for a stroke. Thereafter, he was readmitted to the hospital on two separate

occasions on June 13, 2014 and July 8, 2014 with complaints of stroke-related symptoms and was eventually diagnosed with and treated for the stroke. Dr. Humbert testified that, at the time of the first AndroGel prescription, Mr. Natale had "low normal" total testosterone, which Dr. Humbert attributed to his age. At his deposition, Mr. Natale testified that he was prescribed AndroGel primarily for sexual performance. According to Mr. Natale's medical records, he enjoyed excellent health and was quite active.

At the time Mr. Natale suffered a stroke, he had mild atherosclerotic risk factors. Moreover, his lipid profile was normal up until the time of his stroke. He was not previously diagnosed with either hyperlipidemia or dyslipidemia nor did his physicians treat him for it. While diabetes is considered a risk factor for cardiovascular events, at no time were his A1c levels within what is considered to be the diabetic range. He also has a remote history of sleep apnea for which he was diagnosed and treated more than a decade prior to his stroke. There is no indication that his sleep apnea returned or was untreated. His stroke has required subsequent treatments and created further stroke related complications. It is Plaintiff's belief that the law of Pennsylvania should apply.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Mr. Natale lived in Springfield, Pennsylvania at all relevant times. He was prescribed and used AndroGel in Pennsylvania and he suffered his stroke in Pennsylvania. Mr. Natale filed his complaint on May 31, 2016, less than two years after suffering his stroke and within Pennsylvania's two-year statute of limitations for personal injury actions. A few years later, Mr. Natale moved to New Jersey, where he now resides.

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Mr. Natale's AndroGel prescription was off-label as there is no evidence that he had either primary or secondary hypogonadism. Mr. Natale was first prescribed AndroGel at age 65 based on (1) his report that he had "erectile dysfunction" and (2) his "low normal" total testosterone, which was 280 ng/dL. He has not been diagnosed with any underlying condition that would cause him to have acquired or congenital hypogonadism.

4. Gordon Abraham, 15-cv-05009 – Plaintiff Pick

A. Case Summary

Gordon Abraham was first prescribed AndroGel 1% on October 22, 2008. He stopped and started AndroGel use based on physician recommendation to monitor T levels and see if it was necessary to stay on TRT. On July 18, 2010, he restarted AndroGel 1%, and continued to fill prescriptions and use it up through his myocardial infarction on May 18, 2013. Immediately prior to starting AndroGel his testosterone level was 256 ng/dl and he was diagnosed with

hypogonadism, though he was not diagnosed with primary or secondary hypogonadism, nor any specific condition resulting in hypogonadism.

On May 18, 2013, he was diagnosed with an acute myocardial infarction. He had been mowing his lawn and felt chest pain and shortness of breath and went immediately to the hospital. He was taking AndroGel at the time of injury. He had no prior history of myocardial infarction and has not had another one since.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Mr. Abraham has continuously lived in Missouri at all relevant times and was prescribed and treated in Missouri. Missouri has a 5-year statute of limitations for personal injury actions. His injury was May 18, 2013 and the complaint was filed June 8, 2015.

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Mr. Abraham's prescription of AndroGel was off-label as there is no evidence that he had either primary or secondary hypogonadism. He complained of symptoms of fatigue libido and sexual function. His testosterone was tested to be 256. He was never diagnosed with any underlying cause of low testosterone.

5. Dick Bechtholdt, 15-cv-09652 – Defense Pick

A. Case Summary

Mr. Bechtholdt has a remote history of intramuscular testosterone use for a period of approximately eight (8) months from 1998-1999. Mr. Bechtholdt did not restart testosterone supplementation until 2012, when he began Testosterone Cypionate injections after a blood test revealed his testosterone level was 203. Because Mr. Bechtholdt traveled and split his residency between Iowa and Arizona, he was then switched to AndroGel. On May 10, 2012 he filled his first AndroGel 1.62% prescription for 1 pump, once daily. On June 29, 2012, Mr. Bechtholdt's prescription was doubled to 1 pump, twice daily after a subsequent blood test revealed his testosterone level was 237.

On October 6, 2012, at 67 years old and on AndroGel, Mr. Bechtholdt presented to Iowa Methodist Medical Center where he was diagnosed with an Acute Myocardial Infarction secondary to 30% mid vessel stenosis to LAD; 50% proximal stenosis of circumflex artery; and 100% proximal stenosis of the right coronary artery. Intervention was performed with drug-eluting stent deployment. This is the only heart attack that he has experienced.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Mr. Bechtholdt stopped using AndroGel on November 5, 2013 (1 year and 1 month after his heart attack) while he was in the hospital for a knee replacement surgery and he saw a news segment on television, linking cardiovascular events to the use of TRT. Mr. Bechtholdt filed his complaint on October 29, 2015, less than two years after discovering the link between cardiovascular events and the use of TRT and within Iowa's and/or Arizona's two-year statute of limitations for personal injury actions.

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Mr. Bechtholdt's prescription was off-label as there is no evidence that he had either primary or secondary hypogonadism. Mr. Bechtholdt was prescribed AndroGel 1.62% based on decrease in energy and mild sexual dysfunction; he was subsequently diagnosed with hypogonadism. While Mr. Bechtholdt was never diagnosed with primary or secondary hypogonadism, a single remote medical record from the late 1990s mentions that Mr. Bechtholdt had small testicles. However, Dr. Stacy Childs, who was Mr. Bechtholdt's urologist from the late 1990s, testified that although Mr. Bechtholdt had smaller than average testicles he did not suffer from either Klinefelter's syndrome or vanishing testes syndrome.

6. George Kibat, 15-cv-08820 – Defense Pick

A. Case Summary

George Kibat was first prescribed AndroGel 1% on August 5, 2011 by his primary care physician after presenting with consistent and severe fatigue. He was 60 years old at the time. At some point in June 2012, Mr. Kibat switched over to Androgel 1.62%. Mr. Kibat consistently filled his prescription for AndroGel 1% and 1.62% and used AndroGel 1% and 1.62% from August 5, 2011 to February 4, 2013. Mr. Kibat's AndroGel use was preceded by two Depo-T shot administrations: one in August 2010; and one July 2011. Mr. Kibat's primary physician noted that he was taking a blood test to test Mr. Kibat's testosterone levels in August 2010 due to decreased libido. This blood test revealed that Mr. Kibat's total testosterone level was 146 ng/dL.

Mr. Kibat experienced a first heart attack on June 30, 2010, before ever taking AndroGel. On April 5, 2012, while taking AndroGel 1%, Mr. Kibat experienced a second heart attack. On that day, Mr. Kibat presented to the hospital with intermittent chest burning and left arm pain. He was also experiencing nausea and vomiting. He was diagnosed with and treated for an acute anterior ST elevation myocardial infarction, including a PTCA and the placement of a stent. He was discharged from the hospital on April 7, 2012. At the time of his second heart attack, Mr. Kibat was a retired, unmarried truck driver. Additionally, Mr. Kibat had a medical history that

also included smoking, COPD, family history of cardiac disease, hyperlipidemia, and mental health disorders.

Mr. Kibat continued to use AndroGel after his second heart attack. Expert and physician testimony establishes that Mr. Kibat's second heart attack – induced by AndroGel – was a much more serious event than the first, resulting in extended care and treatment that included placement of a defibrillator and permanent, irreversible damages.

B. No Statute of Limitations or Statute of Repose Defenses Available to AbbVie

There should be no statute of limitations or statute of repose defenses available to AbbVie. Mr. Kibat lived in Iowa at the time of his AndroGel prescriptions and his second heart attack. Mr. Kibat filed his complaint on October 5, 2015, more than two years after suffering his second heart attack; however, Iowa employs a discovery rule that permits Mr. Kibat's 2015 filing as that date was within two years of his learning of his potential action against AbbVie.

C. Additional Defenses Available to AbbVie

Plaintiff is not aware of any additional defenses available to AbbVie other than the alleged case specific medical causation defenses set forth in AbbVie's case specific expert report.

D. Off-Label AndroGel Prescription

Mr. Kibat's AndroGel prescription was off-label as there is no evidence that he had either primary or secondary hypogonadism. Mr. Kibat was prescribed AndroGel 1% based on: (1) reporting to his doctor that he was severely fatigued and had a decreased libido; and (2) a single testosterone test revealing a total testosterone reading of 146 ng/dL. While Mr. Kibat was not diagnosed with primary hypogonadism or hypogonadotropic hypogonadism, his prescribing physician would not testify that the prescription was written off-label and specifically rejected that Mr. Kibat had been prescribed AndroGel for age-related hypogonadism.

AbbVie Defendants' Position

AbbVie understands the Court's first topic to be limited to men with hypogonadism (primary and/or secondary) due to medical conditions specifically listed as potential causes in the label.[1] With that in mind, AbbVie notes that in *Abraham*, the prescriber Dr. Biber testified that

[1] However, as the Court is aware, AbbVie believes that the approved indication has always been (until May 2015) for all men with hypogonadism regardless of the underlying specific cause (or all men with low or no testosterone) and will present such evidence, including from each plaintiffs' prescribers (e.g., the *Kibat* prescriber diagnosed plaintiff with hypogonadotropic hypogonadism (Dr. Sheppard Dep. Tr. at

he prescribed AndroGel for "hypogonadism" and that Mr. Abraham possibly had "orchitis," caused by epididymitis, that may have contributed to his hypogonadism. Biber Tr. at 20:3-9, 33:14- 35:10. Dr. Biber did not confirm orchitis because that would require an invasive procedure, but believed it possibly was the cause of Mr. Abraham's hypogonadism because he had epididymitis which Dr. Biber said is "often" associated with orchitis. *Id.* at 109:11-110:4.

With respect to the second topic, based on current information, AbbVie does not anticipate moving for summary judgment as to any of the Trial Group 1 cases based on statute of limitations or statute of repose defenses, or any other unique defenses (except possibly based on state law differences).[2] However, assuming dispositive motions are denied, the *Abraham* case may implicate a statute of limitations defense at trial.[3]

Dated: June 14, 2018

Respectfully submitted,

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66:12-68:12) and the *Harris* prescriber diagnosed plaintiff with primary hypogonadism due to testicular failure (Dr. Ehret Dep. Tr. at 152:22 to 153:19)).

[2] AbbVie will be filing as to each of the TG1 cases, case-specific motions for summary judgment based on Plaintiffs' inability to prove essential elements of their claims, and *Daubert* motions to exclude the Plaintiffs' general and case-specific experts on June 14, 2018.

[3] For completeness of information, the Court is of course familiar with the parties' positions in the event of a retrial of the *Konrad* case, for which post-trial motions are fully briefed, and the trial readiness of the *Frost* case.

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Brendan A. Smith

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